

MAY - 1 2001

K010494

510(k) Summary of Safety and Effectiveness Information
Sysmex ® Automated Coagulation Analyzer CA-1500
February 16, 2001

Dade Behring Inc.
7739 NW 48th Street
Miami, FL 33166

Contact Person: Radames Riesgo at 305.392.5639 or by facsimile at 305.392.5638.

Trade or Proprietary Name: Sysmex® Automated Coagulation Analyzer CA-1500

Common or Usual Name: Automated Coagulation Instruments

Classification Name: Coagulation instrument (21 CFR §864.5400)

Registration Number: *Manufacturing Site*
Sysmex Corporation
Kobe, Japan 9613959

Importer
Sysmex Corporation of America
One Wildlife Way
Long Grove, IL 60047-9596 1422681

Distributor
Dade Behring Inc.
Glasgow Site
P.O. Box 6101
Newark, DE 19714-6101 2517506

The CA-1500 is substantially equivalent in intended use and technological characteristics to the Behring Coagulation Timer (BCT), Dade Behring, Marburg, Germany which was cleared by FDA under Document Control No. K955278.

As demonstrated by clinical correlation studies, the performance claims of the proposed device are similar to the predicate device. During those studies, specimens were evaluated from apparently healthy individuals and from patients with different pathological conditions which are expected to affect the results for a particular assay. The following summary shows the results of the comparison studies between the proposed and the predicate device.

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**Summary of Method Comparison Studies Between
CA-1500 and BCT**

Test	Sample Number (n)	Coefficient of Correlation (r)	Regression Equation
Batroxobin Time	126	0.993	$Y = 0.88X + 5.24$

**Summary of Precision Studies
Sysmex® Automated Coagulation Analyzer CA-1500**

Assay	Control Level	n	Mean	Within Run %CV	Between Run %CV	Total %CV	Max. Error Criteria %CV
Batroxobin Time	CPN	40	19.6	0.8	0.5	1.0	10
	PP*	32	25.1	2.7	3.3	4.1	

*Pathological plasma pool



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Radames Riesgo
Manager, Regulatory Affairs and Compliance
Dade Behring, Inc.
7739 NW 48th Street
Miami, Florida 33166

Re: K010494
Trade Name: Sysmex® Automated Coagulation Analyzer CA-1500
Regulation Number: 21 CFR § 864.5425 and 21 CFR § 864.8100
Regulatory Class: II
Product Code: JPA
Dated: February 16, 2001
Received: February 20, 2001

Dear Mr. Riesgo:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

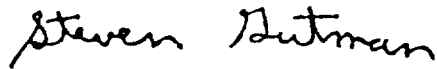
A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K010 494

Device Name: Sysmex® Automated Coagulation Analyzer CA-1500

Indications for Use:

The intended use of the Sysmex® CA-1500 is as a fully automated, computerized blood plasma coagulation analyzer for *in vitro* diagnostic use in clinical laboratories.

The instrument uses citrated human plasma to perform the following parameters and calculated parameters:

Clotting Analysis Parameters

- Prothrombin Time (PT)
- Activated Partial Thromboplastin Time (APTT)
- Fibrinogen (Clauss)
- Batroxobin Time
- Extrinsic Factors (II, V, VII, X)
- Intrinsic Factors (VIII, IX, XI, XII)
- Protein C

Chromogenic Analysis Parameters

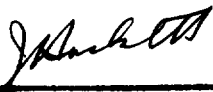
- Antithrombin III
- Factor VIII
- Plasminogen
- Heparin
- Protein C
- α 2-Antiplasmin

Calculated Parameters

- PT Ratio
- PT INR
- PT %
- Derived Fibrinogen
- Factor Assays % Activity

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K010 494

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use _____
(Optional Format 1-2-96)